

Claim 6, line 1, delete "calim" insert "--claim--".

### REMARKS

Reconsideration of this application is requested. Claims 1-3 and 5-7 are active in the application subsequent to entry of this amendment.

The specification and claims have been amended for purposes of clarity and to respond to the rejection under 35 U.S.C. §112, second paragraph. A systematic transcription error or artifact of translation is present in the specification and claims of this application. The term "rate" was used instead of – ratio – as is common when referring to proportions of two components. As an illustration of the proper form of presentation see claim 1 of the Menz patent, of record, discussed below. With regard to the "middle" chain length fatty acids, or course – medium—chain length fatty acids was intended, as the examiner correctly assumes, and is commonly used in this art, for example the Babayan patent (among others), of record, also discussed below.

The claims have been amended to attend to the above two items and to correct the spelling of "claim" as noted in the Official Action. In addition, the subject matter of claim 4 has been incorporated into claim 1 thus providing an additional characteristic for applicants' compositions in the main claim. Also, the term "composing" has been changed to the more traditional – comprising – in claim 1.

To summarize the content of the claims, the invention of amended claim 1 is an oil or fat composition composed chiefly of triglycerides and is characterized by three properties:

(1) the ratio of medium-chain fatty acids in all the fatty acids comprising the oil or fat composition is 5 to 23% by mass,

(2) the ratio of triglycerides having two medium-chain fatty acid residues in the molecule in all the triglycerides is 1 to 20% by mass, and

(3) the ratio of long-chain saturated fatty acids in all the long-chain fatty acids comprising the oil or fat composition is 20% by mass or less.

Therefore, in order to defeat novelty of amended claim 1, at least all of these three features must be described in a single prior art document.

The object of the invention of claim 1 is to provide an edible oil or fat composition which is less accumulated as body fat due to the ratio of medium-chain fatty acids (1) and triglycerides (2) as explained in applicants' specification at page 6, lines 18-27. In addition, applicants' edible oil or fat composition exhibits good stability at low temperatures (see page 7, lines 8-16).

Claim 2 specifies the medium-chain fatty acids are saturated fatty acids having 6-12 carbon atoms.

Claim 3 provides that the ratio of triglycerides having three medium-chain fatty acid residues in the molecule in all the triglycerides composing the oil or fat composition is 3% by mass or less.

Claim 5 relates to the oil or fat composition of claim 1 which further contains as emulsifiers at least one kind of sucrose fatty acid ester, polyglycerol fatty acid ester, succinic acid monoglyceride, monoglyceride, diglyceride, sorbitol fatty acid ester and sorbitan fatty acid ester. The emulsifier is present in an amount of 0.1 to 6% by mass based on the oil or fat composition (before the incorporation of the emulsifiers).

Claim 6 is directed to a preferred combination of the emulsifiers.

Claim 7 relates to an oil or fat composition for cooking containing the oil or fat composition of claim 1.

The Official Action contains seven separate prior art-based rejections on seven separate references – all are based upon alleged anticipation. Only the first three rejections include original claim 4 (now incorporated into claim 1). While particular emphasis is placed on Kashiwabara, Babayan and Hunter, for completion of the record all of the applied references are discussed. However, it is counsel's understanding the rejections based upon Senda, Benita, Menz and Nokaly are no longer pertinent.

Kashiwabara (U.K. 2,090,115) describes low-residue diet type nutrient composition containing as core ingredients a protein source, fat source, carbohydrate source and, as desired, other nutritive component(s). The composition contains 20 to 40% by weight, based on the total weight of the protein, fat and carbohydrate sources and the other nutritive components, skim milk powder as part of the protein source and 5 to 15% by weight, based on the total weight of the protein, fat and carbohydrate sources and the other nutritive components, of medium chain triglycerides as part of the fat source. The skim milk powder contains 5 to 30% by weight of lactose (claim 1). In the passage at page 2, lines 15 and 29 (referred to by the examiner) the reference states that the carbon number of the medium-chain fatty acids of the medium chain triglycerides is 6 to 10, and the content of the medium-chain triglycerides is 5 to 15% by weight, respectively. Considering the above amended claims, there are several deficiencies in the disclosure of this reference. First, Kashiwabara is silent on characteristic (2). The medium chain triglycerides referred to in Kashiwabara are deemed to be triglycerides having *three* medium-chain fatty acid residues in the molecule. In any event, Kashiwabara contains no description of triglycerides having *two* medium chain fatty acid residues in the molecule (the other one is usually a long-chain fatty acid residue).

Kashiwabara is also silent as to characteristic (3), that is Kashiwabara has no description of long-chain fatty acids.

Further, Kashiwabara has no description of characteristic (1). The ratio of the medium chain triglycerides in Kashiwabara is an amount based on the combined weight of the protein source, fat source, carbohydrate source and other nutritive component(s), whereas the ratio referred to in (1) above is the ratio of medium-chain fatty acids in all the fatty acids comprising the oil or fat composition. The two are utterly different in the basis for calculating the value. If one assumes *arguendo* in Kashiwabara that the fat source is medium-chain triglycerides alone, the ratio referred to in above (1) becomes 100% by mass, and becomes widely out of the range of (1). Thus, Kashiwabara does not defeat the novelty of claim 1 of the present application. Nor is the novelty of claim 2 denied because it is subordinate to claim 1.

In addition to being novel, applicants' claims are inventive over disclosures of this citation. Specifically Kashiwabara does not have anything in common with the invention of claim 1 of the application.

Babayan (U.S. 4,952,606) claims a composition useful for nutritional applications containing a transesterification product of a mixture consisting essentially of 10-90% by weight dairy fat, 10-50% by weight additional medium-chain triglycerides and 0-80% by weight additional long-chain triglycerides, or hydrolysis products thereof (claim 1). It is described in column 2, lines 6-9 and 50 referred to by the examiner that the content of the additional medium-chain triglycerides may be 0-90% by weight and the carbon number of the medium-chain fatty acids of the medium-chain triglycerides is 6-12 (primarily 8 and 10), respectively.

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However, characteristic (3) of claim 1 of the present application cannot be found in Babayan. The reason is that Babayan states that polyunsaturated long-chain triglycerides are preferred as the long-chain triglycerides (see column 2, line 9), but is silent as to the possible presence of any long-chain saturated fatty acids and their use ratio. Further, since Babayan has no description of triglycerides having two medium-chain fatty acid residues in the molecule and their use ratio, characteristic (2) is also not anticipated by Babayan. Further, since the amounts in Babayan and the value in characteristic (1) are different in their basis of calculation, the Official Action has not clearly demonstrated characteristic (1) is anticipated by Babayan.

Thus, claims 1 and 2 are novel over the disclosure of Babayan.

In addition to being novel, applicants' claims are inventive over the disclosures of this citation. Specifically, the invention of Babayan lies in providing a composition for nutrition support of hypercatabolic patients, for example patients following surgery (column 1, lines 43-50). By contrast, the object of the invention of claim 1 of the application lies in providing an edible oil or fat composition having reduced accumulation in body fat (page 6, lines 18-27) and having good stability at low temperatures (page 7, lines 8-16). The objects and composition of the present invention are different thus applicants' claims are patentable over the disclosures of Babayan.

Hunter (U.S. 4,863,753) claims a peanut butter comprising a dispersion of finely divided peanut particles in a continuous oil phase, in which the oil phase includes triglycerides containing at least 30% by weight (10% by weight in Summary of the Invention) medium chain fatty acids (claim 1). It is described in column 3, lines 26-32 referred to by the examiner that the "medium chain fatty acids" mean caproic acid ( $C_{6:0}$ ), caprylic acid ( $C_{8:0}$ ) and capric acid ( $C_{10:0}$ ), and it is described in column 5, lines 42-52 that the "triglycerides" have, for example, the following composition:

- (a)  $C_6$ - $C_{10}$  saturated fatty acids                      15-70% by weight
- (b)  $C_{17}$ - $C_{26}$  unsaturated fatty acids                      0-20% by weight
- (c)  $C_{17}$ - $C_{26}$  saturated fatty acids                      3-65% by weight
- (d) ~~Fatty acids selected from  $C_{12}$ - $C_{16}$  saturated fatty acids,  $C_{12}$ - $C_{16}$  unsaturated fatty acids~~  
and their mixtures 0-10% by weight.

First, Hunter is silent as to characteristic (2). Namely, Hunter does not describe anything at all about triglycerides having two medium-chain fatty acid residues in the molecule and their use ratio. As to characteristic (3), the ratio of the long chain saturated fatty acids to all the long chain fatty acids can range from the minimum 13% by weight [(b)=20, (c)=3, (d)=0] to the maximum 100% by weight [(b)=0, (c)=65, (d)=0], which partially overlaps with the range of the above (3) [20% by mass (the same with % by weight) or less]. However, by far the greater part of both ranges is different from each other. Moreover, there is no description in Hunter to suggest that the 20% by weight or less indicates good stability at low temperatures. Applicants do not believe that the Official Action provides a basis for arguing the above description of Hunter anticipates characteristic (3).

Also, as to the characteristic (1), in Hunter, the ratio of medium chain fatty acids in all the fatty acids comprising the triglycerides can range from the minimum 15% by weight ((a)=15, (d)=0) to the maximum 80% by weight ((a)=70, (d) is a  $C_{12}$  saturated fatty acid and 10), and partially overlaps with the range of the above (1) (5 to 23% by mass). Again, by far the greater part of both ranges are different from each other.

Moreover, there is no description in Hunter to suggest that the 5 to 23% by weight would result in low body fat accumulation. Applicants do not believe that the Official Action provides a basis for arguing that the above description of Hunter anticipates characteristic (1). Applicants' claims as above amended are novel over Hunter

In addition to being novel, applicants' claims are inventive over the disclosures of this citation. Specifically the object of the invention of Hunter lies in providing a reduced calorie peanut butter, and further a reduced calorie peanut butter having an excellent consistency (column 2, lines 20-30). On the other hand, the object of the invention of claim 1 of the present application lies in providing an edible oil or fat composition which is less accumulated as body fat (page 6, lines 18-27) and has good stability at low temperatures (page 7, lines 8-16). Therefore, since the object and compositions of the invention are different applicants' claims are both novel and inventive over the disclosures of Hunter.

Senda (U.S. 5,006,359) describes a storage stable aqueous emulsion comprising, based on the total amount of the emulsion,

(a) 2-10% by weight of an edible oil comprising saturated medium-chain fatty acid triglycerides,

(b) 0.1-1% by weight of a certain emulsifying agent,

(c) 2.0-4.0% by weight of a certain stabilizer,

(d) 20-40% by weight of a sweetener, and

(e) 40-70% by weight of water

(as stated in claim 2). In Table 1 referred to by the examiner, the composition of the starting materials of the aqueous emulsion is exemplified, and the relative amounts of the medium-chain fatty acid triglycerides are 6% by weight in both Samples 1 and 2.

However, the values in Senda's emulsion are based on the total contents of the emulsion not just the fat content, whereas the value of (1) of claim 1 of the present application is based on all the fatty acids comprising the oil or fat composition, thus both values are based on completely different calculations. Therefore, the values of 2-10% by weight and 6% by weight have no relation to the value of (1). In this connection, when the ratio of (1) is calculated on Table 1, since all the fatty acids comprising the aqueous emulsion are only medium-chain fatty acids from the medium-chain fatty acid triglycerides and stearic acid from the hexaglycerin monostearate, the calculated value becomes far different from the range of (1). Further, Senda is completely silent as to characteristics (2) and (3). Namely, Senda contains no description of triglycerides having ~~two medium-chain fatty acid residues in the molecule, their use ratio and long-chain~~ saturated fatty acids nor their use ratio. Thus, claim 1 (and claims 2, 3, 5 and 6 as its subordinate claims) are not anticipated by Senda

Additionally, the value of claim 3 of the present application (3% by mass or less) is the ratio of triglycerides having three medium-chain fatty acid residues in the molecule in all the triglycerides comprising the oil or fat composition, is utterly different from the values in Senda's emulsion on the basis of calculation. Namely, since, in Senda, only saturated medium-chain fatty acid triglycerides are used as triglycerides, the value corresponding to claim 3 of the application becomes 100% by weight which is completely out of the range of claim 3 of the present application.

In addition to being novel, applicants' claims are inventive over the disclosures of this citation. Specifically Senda's object lies in providing a premix preparation capable of stably maintaining an emulsified state and is preservable over a long period (abstract). By contrast the object of the invention of claim 1 of the present application lies in providing an edible oil or fat composition which is less accumulated as body fat and has good stability at low temperatures. Therefore, since the objects and compositions are different, applicants' claims are both novel and inventive over the disclosure of Senda.

Benita (U.S. 5,364,632) discloses an oil in water type emulsion pharmaceutical composition which comprises an effective amount of a lypophilic drug. The composition contains 3 to 50% by w/v of an oily carrier consisting of MCT oil optionally in combination with vegetable oil, 0.05 to 20% by w/v of a phospholipid, 0.03 to 10% by w/v of a non-ionic surfactant, and 0.05-5% by w/v of an ionic surfactant selected from bile-duct surface active agent, cholic acid and their derivatives (abstract). Column 3, lines 21-35 referred to by the examiner, includes essentially the same description as in the abstract (but 0.5-20% by w/v of a phospholipid, 0.3 to 10% by w/v of a non-ionic surfactant and 0.5-5% by w/v of an ionic surfactant).

However, characteristics (2) and (3) of the present invention as defined in applicants' claim 1 are not described in Benita et al. Namely, Benita does not disclose triglycerides having two medium-chain fatty acid residues in the molecule and their use ratio nor long-chain saturated fatty acids and their use ratio. Further, it is doubtful if characteristic (1) can be said to be described in Benita. The reason is that the basis for calculating the value of (1) is completely different from the basis for calculating the value of the 3 to 50% by w/v of an oily carrier consisting of MCT oil. Thus, claim 1 (and claims 2, 3, 5 and 6 as it subordinate claims) are novel over Benita.

In addition to being novel, applicants' claims are inventive over the disclosures of this citation. Specifically, the object of the invention of Benitz lies in providing a pharmaceutical oil-in-water type emulsion containing hydrophobic drugs, which composition is stable over prolonged storage, and, where the drug is heat resistant, can be sterilized by autoclaving without a change in its properties or loss of its stability (column 1, lines 60-68). By contrast the object of the invention of claim 1 of the present application lies in providing an edible oil or fat composition which is less accumulated as body fat and has good stability at low temperatures. Therefore, since the objects and compositions of the invention are different, the claims of the present application are both novel and inventive over the disclosures of Benita.



Menz (U.S. 3,658,555) claims a mixture of glycerides of saturated C<sub>8</sub> and C<sub>10</sub> fatty acids consisting essentially of tricaprin and monocaprylodicaprin. The tricaprin is present in the amount of 45-95% by weight of the mixture, the total of tricaprin and monocaprylodicaprin is at least 80% by weight of the mixture, the ratio of tricaprin to monocaprylodicaprin is 45-95 parts by weight to 40-5 parts by weight. At least 20% of the mixture of glycerides is in the  $\beta$ -crystal form, the mixture of glycerides containing substantially no monoglycerides and not more than 20% of C<sub>8</sub> and C<sub>10</sub> diglycerides (claim 1). This mixture is said to have good spreadability, is excellent in oxidation resistance (column 1, line 67-column 2, line 21), and is used as part of the fat phase of margarine (claim 9). Claim 9 recites a margarine consisting essentially of 80% by weight of a fat phase and 20% by weight of an aqueous phase, where the fat phase includes the above mixture.

Table 1, line 1 referred to by the examiner describes an emulsion consisting of 8.5% by weight of tricaprin, 27.3% by weight of monocaprylodicaprin and the residual water. Applicants do not understand why Menz can be novelty-defeating. According to applicants' understanding of the disclosure, Menz does not anticipate any of characteristics (1), (2) and (3) of claim 1. Also, Menz does not have anything in common with the invention of applicants' claim 1.

El-Nokaly (U.S. 5,192,572) claims a process for lowering the fat absorption of fried potato pieces by frying potato pieces in an oil comprising 0.1-2% by weight silica and 98-99.9% by weight oil. The silica is a hydrophilic silica with a particle size of 7-100,000 nm (claim 1). In column 4, lines 23-40 referred to by the examiner the reference states, as one of oils preferred to be used in the above process, reduced calorie fats comprising at least 15% by weight triglycerides selected from MML, MLM, LLM and LML triglycerides (M: C<sub>6</sub>-C<sub>10</sub> saturated fatty acids, L: C<sub>16</sub>-C<sub>26</sub> saturated fatty acids) and mixtures thereof.

However, El-Nokaly does not anticipate characteristic (3) of claim 1 of the application. Namely, El-Nokaly has no description on the ratio of long-chain saturated fatty acids in all the long-chain fatty acids. Also as to characteristic (1), the bases for calculation are different and it is not clear if the above 15% by weight falls within the range of (1). Thus, claim 1 of the application is novel over El-Nokaly, and the novelty of claim 7 using the oil or fat composition of claim 1 is also apparent over El-Nokaly.

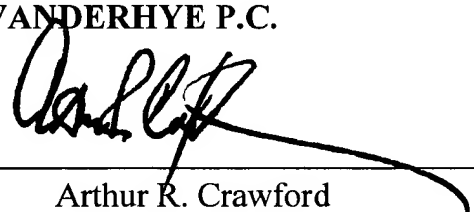
In addition to being novel, applicants' claims are inventive over the disclosures of this citation. Specifically the effect of the fat described in El-Nokaly is reduced calories, whereas the object/effect of the invention of claim 1 of the application lies in providing an edible oil or fat composition which is less accumulated as body fat and has good stability at low temperatures. Therefore, since the object/effect and compositions are different, applicants' claims are both novel and inventive over the disclosures of El-Nokaly.

Reconsideration and favorable action are solicited.

Respectfully submitted,

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